

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/423,109	PARIS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	SABIHA QAZI	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 11/14/11.
2.  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.
3.  The allowed claim(s) is/are 3,4,7,8 and 18.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**

7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 07/29/03; 12/07/09 (date of publication of  
NPL 22 is added).
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application
6.  Interview Summary (PTO-413),  
Paper No./Mail Date 12/07/11.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

/Sabiha Qazi/  
Primary Examiner, Art Unit 1628

**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney John P. White on 12/08/11.

This application has been amended as follows:

Claim 18 is amended as follows:

Please delete "effect" before "hormonal replacement therapy" from line 7 in claim 18 and replace it by "achieve".

Please insert a "," after "mucosa" in line 8 of claim 18; delete "and" after "," before "inducing" in same line 8; delete "and maintaining" after "inducing" from line 8.

Please insert ", and keeping the uterine mucosa in an atrophic condition" after endometrial atrophy in line 9.

Amended claim 18 will read as follows:

18. (As now amended) A hormonal replacement therapy method for treating an estrogen deficient, menopausal woman comprising orally administering daily without interruption to such menopausal woman a composition containing from 0.5 to 1.5 mg of free estradiol or

1.5 to 2 mg of an estradiol ester, and from 0.625 to 1.25 mg of nomegestrol acetate per daily dose so as to achieve hormonal replacement therapy while preventing growth of uterine mucosa, inducing endometrial atrophy, and keeping the uterine mucosa in an atrophic condition.

**Reasons for Allowance**

1. The following is an examiner's statement of reasons for allowance:
2. Claims 3, 4, 7, 8 and 18 are allowed.
3. Prior art of record does not teach not suggest unexpected results as presented in table 2 on page 24 of specification. The data shows histological appearance of the endometrium after 6 months of continuous treatment of estradiol valerate and nomegestrol. The data as presented clearly shows that combination therapy of estradiol valerate using 0.625 to 1.25 mg of nomegestrol acetate shows unexpected results.
4. Claim 18 is re-numbered as claim 1; all other claims depend on it.

Examiner thanks Attorney John P. White for his cooperation during the prosecution of this application.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

**Communication**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SABIHA QAZI whose telephone number is (571)272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fetterolf Brandon can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/  
Primary Examiner, Art Unit 1628